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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,078	04/25/2001	Olivier De Lacharriere	016800-438	6852
7590	10/21/2005		EXAMINER	
Norman H. Stepno BURNS, DOANE, SWECKER & MATHIS, L.L.P. P.O. Box 1404 Alexandria, VA 22313-1404			YU, GINA C	
			ART UNIT	PAPER NUMBER
			1617	
DATE MAILED: 10/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/841,078	LACHARRIERE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Gina C. Yu	1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 10 June 2005.

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## **Disposition of Claims**

4)  Claim(s) 19,20 and 23-48 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 19,20 and 23-48 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)  Notice of References Cited (PTO-892)  
2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3)  Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.  
4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.  
5)  Notice of Informal Patent Application (PTO-152)  
6)  Other: \_\_\_\_\_.  
\_\_\_\_\_

## DETAILED ACTION

### ***Election/Restrictions***

Receipt is acknowledged of response to election of species required, filed on June 8, 2005. Applicants have selected lisophylline as the TNF-alpha antagonist and depigment agent as the at least one agent that causes an irritant side effect. Since no prior art is found to anticipate or render the claimed invention as elected, the search was extended to other species of the Markush group.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

**Claims 19-, 20, 23-48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. 5658581 and US 5895649.**

The '581 patent claims a composition comprising a histamine antagonist, an interleukin-1-anagonist and/or a TNF alpha antagonist anti-irritant agent selected from the group consisting of auranofin, lactoerrin, lisophylline, sulphasalazine, and 6, 7-

dihydro-2-[4-(methylsulfinyl)phenyl]-3-(4-pyridinyl)-5H-pyrrolo[1,2-a]imidazole, and combination thereof, and at least one compound which produces an irritant side effect in a dermatologically, pharmaceutically and cosmetically acceptable medium. See instant claims 31, 32, Claim 2 recites the irritants of claim 1, which also overlap with the irritant agents of claim 19 of the instant application, which include alpha-keto acids, beta-keto acids, retinoids, anthralins, anthranoids, peroxides, minoxidil, lithium salts, anti-antimetabolites, vitamin D, depigmentation agents. See instant claims 19, 30, 38-48. The "dermatologically, pharmaceutically and cosmetically acceptable medium" is defined as aqueous or anhydrous gel, oil-in-water emulsion, serum, microcapsules, microparticles of vesicular dispersions. See '581, col. 5, lines 44 – 56; instant claims 27 and 35. Claims 28, 29, 36, and 37 are met by the active agents limitation in claim 3 of the patent. The '581 patent also defines the amount of the anti-irritant agent "sufficient to antagonize this irritant side effect" in col. 5, lines 37 – 43. See instant claims 25, 26, 3, and 34.

Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to compositions of overlapping limitations as discussed above.

The '649 patent claims a method of using treating neurogenic red skin patches and rosacea comprising topically applying a composition comprising, at least one TNF-alpha antagonist and at least one selected from the Markush group of the dermatologically/pharmaceutically active agents that overlap with the irritant agents recited in the instant claims 19. Since the composition that is claimed in the instant

application is already disclosed in the claims of '649, the present invention is viewed an obvious variation of the patented invention.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 571-272-8605. The examiner can normally be reached on Monday through Friday, from 8:30 AM until 6:00 PM..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gina Yu  
Patent Examiner



SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER